3289. Misbranding of Dr. Morse's Indian Root pills and Comstock's Dead Shot worm pellets. U. S. v. 469 Packages, etc. (F. D. C. No. 26044. Sample Nos. 2075-K, 2076-K.)

LIBEL FILED: December 3, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about November 4 and December 30, 1947, and January 27, March 22 and 30, June 14, and September 7, 1948, by W. H. Comstock Co., Ltd., from Morristown, N. Y.

PRODUCT: 469 packages of Dr. Morse's Indian Root pills and 142 packages of Comstock's Dead Shot worm pellets at Washington, D. C.

LABEL, IN PART: (Package) "Dr. Morse's Indian Root Pills (Improved) * * * Active Ingredients: Aloes, Mandrake, Gamboge Jalap, Cayenne Pepper Contents 40 Pills" and "Comstock's Dead Shot Worm Pellets * * * Contains 10 Pellets * * * Active Ingredients Ext. Pepo Spigelia (Pink Root)."

NATURE OF CHARGE: Dr. Morse's Indian Root pills. Misbranding, Section 502 (a), the following statements in the leaflet entitled "The Joy of Living" accompanying the article were false and misleading since the article was not capable of fulfilling the promises of benefit stated and implied by such statements: "The manufacturers of Dr. Morse's Indian Root Pills have compounded this laxative to assist man when he overindulges in eating or drinking, and through the lack of proper exercise, by helping to renew his interest in life * * * It pays to be regular * * * We moderns eat, drink or smoke too much, eat too quickly, do not have sufficient sleep-too little fresh air and exercise. As a result we become constipated. You should watch for these signs: Sick headache, dizziness, sallow skin, fuzzy tongue * * * and that 'gone' tired feeling. Now is the time to get out your box of Dr. Morse's Indian Root Pills (Improved) to get that bowel movement to give you that feeling of pep and to renew your interest in life. Bad Breath-Fuzzy Coated Tongue-Bad Taste in the Mouth-Due to Temporary Constipation-When you feel or see these signs due to temporary constipation, take one or two Dr. Morse's Indian Root Pills (Improved) before and after meals and two to four Pills before going to bed. Continue as required * * * As you grow better, and the movements become regular, take a smaller number of pills until you feel no further need of them * * * Continue until the movements become regular." Further misbranding, Section 502 (a), the designation "Indian Root" in the name of the article was false and misleading since Indians did not make use of this combination of drugs, and the ingredients, aloe and cayenne pepper, are not roots and are not obtained from roots; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against unsafe methods and duration of administration in such manner and form as are necessary for the protection of users since the article was essentially a laxative and its labeling failed to warn that frequent or continued use of the article, or its use in accordance with the following directions appearing in its labeling, may result in dependence upon a laxative to move the bowels: (Package) "Adults-1 to 2 Pills before and after meals and 2 to 4 at bed time" and (leaflet) "Take one to two Dr. Morse's Indian Root Pills (Improved) before and after meals and two to four before going to bed. Continue as required. * * * Constipation * * * Grownups suffering from this trouble should take one to two Dr. Morse's Indian Root Pills (Improved) Before and after each meal and two to four pills before going to bed. Continue until movements become regular or until you have no further need of them. Continue as required."

Comstock's Dead Shot worm pellets. Misbranding, Section 502 (a), the designation on the container and leaflet "Comstock's Dead Shot Worm Pellets for Round and Pin Wo.ms," the statements on the container "This medicine helps to expel the worms," and the statements in the accompanying leaflet "If you are not sure that the worms and their eggs have been removed the same dose should be taken two weeks after the first dose. Thread Worms—In addition to the internal treatment, it will be necessary in the case of Thread Worms to use an enema * * * Delicate, underweight, or frail users should decrease the dose but continue the remedy three or four nights" were false and misleading since the article was not effective for the removal of round worms, pin worms, or thread worms.

DISPOSITION: W. H. Comstock Co., Ltd., claimant, having petitioned for the removal of the case to the Southern District of New York and the Government having consented, an order was entered on January 11, 1949, directing such removal. On May 3, 1950, the claimant having failed to file an answer to the libel, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3290. Adulteration and misbranding of Geo-Mineral. U. S. v. 75 Bottles * * *. (F. D. C. No. 27042. Sample No. 41028-K.)

LIBEL FILED: On or about April 15, 1949, District of Montana.

ALLEGED SHIPMENT: On or about January 27, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 75 3-ounce bottles of Geo-Mineral at Great Falls, Mont., in possession of the Pay Less Drug Store.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated in interstate commerce.

Misbranding, Section 502 (a), the statements appearing on a placard on display in the store of the consignee, "Geo-Mineral — Stomach Ailments — Weak Kidneys — Rheumatic Pains — Arthritis — Neuritis," were false and misleading since the article was not effective in the treatment of these conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 27, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3291. Adulteration and misbranding of Gothestrone. U. S. v. Gotham Pharmaceutical Co., Inc., and Max Grossman. Plea of guilty for corporation and plea of nolo contendere for individual. Fine of \$1,000 against corporation. Sentence of 1 year in penitentiary against individual; sentence suspended and individual placed on probation for 1 year. (F. D. C. No. 28155. Sample Nos. 4736-K, 10057-K.)

INFORMATION FILED: April 28, 1950, Eastern District of New York, against the Gotham Pharmaceutical Co., Inc., Brooklyn, N. Y., and Max Grossman, president of the corporation.